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In the United States Patent and Trademark Office

Appn. Number: 10/604,851
Filing Date: 08/21/2003
Applicant: Janusz M. Buchert
Appn. Title: Thermal Emission Non-Invasive Analyte Monitor
Art Unit: 3737

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November 19, 2003

Information Disclosure Statement

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Attached is completed Form PTO- 1449 and copies of the pertinent parts of the reference cited thereon (excluding US Patents and Patents Applications). Following are comments on these references pursuant to Rule 98:

Buchert [1] shows a method and instrument for the non-invasive detection of an analyte concentration in human body tissue. The Buchert's method and instrument uses **spectral characteristic of the natural infrared body emission** and its characteristics, which include emission of spectral lines characteristic to body fluid analyte and appropriate **changes of monochromatic emissivity** due to concentration changes of tissue analytes.

Buchert [2] shows a method and instrument for **continuously determining human body tissue analyte concentration** by non-invasive measurement of the state of spectral emission characteristics of radiation naturally emitted by human tissue in the infrared spectral region, which can be correlated with tissue analyte concentration.

Fraden [3] shows an electronic non-contacting infrared thermometer and a method for measuring the temperature of an object using the pyroelectric sensor.

Kaiser [4] shows a method and instrument for determining the amounts of metabolic products in blood **using ATR prism and a laser beam**.

Knudson [5-7] shows an apparatus and method for a blood constituent measurement by **measuring the intensity of the testing light** while the fluid spectrally modifies the reference light.

Braig [8] shows a self-emission non-invasive infrared spectrophotometer for monitoring glucose and other blood constituents. The measurements are made by **monitoring infrared absorption** of the desired blood constituent in the long infrared wavelength range. The long wavelength infrared energy emitted by the person as heat is monitored and the **infrared absorption of particular constituents** in the blood is measured at characteristic infrared absorption wavelengths for the constituents. The measurements are preferably synchronized with the systole and diastole of the cardiac

cycle so that the signal contribution caused by veins and tissues (which do not pulse) may be canceled when a ratio of the detected signal is taken.

Braig [9] shows also a method and apparatus where the internal "blackbody" energy level of an infrared emission source such as a vascularized appendage prior to **glucose absorption is measured** and used to compensate temperature dependent effects in the concentration calculation.

Sterling [10-12] shows spectrometric methodology and noninvasive **infrared absorption spectrometer** for non-invasively obtaining optical spectra by transient or steady state subsurface **thermal gradient methodology**. The measure infrared energy is processed into **absorption spectra** and then into a concentration of at least one constituent of the body. Embodiments describe the heating and cooling of the heterogenous body to induce and capture the **transient infrared absorption spectral information.**

Kramer [13] and **Braig** [15] show a spectrometer for the non-invasive generation and capture of **thermal gradient spectra** from human or animal tissue. The spectrometer includes thermal mass for inducing a **transient temperature gradient** in the tissue by conductive heat transfer with the tissue. Also provided is an infrared sensor for **detecting infrared emissions from the tissue as the transient temperature gradient progresses** into the tissue, and for providing output signals proportional to the detected infrared emissions.

Braig [14, 16-18] shows a method and apparatus of determining the analyte concentration of a test sample is described. A **temperature gradient is introduced** in the test sample and infrared radiation detectors measure radiation at selected **analyte absorbance peak** and reference wavelengths. The modulation of the temperature gradient is controlled by a surface temperature modulation. The phase and magnitude differences due to temperature modulation, having a relationship to analyte concentration, are measured, correlated, and processed to determine analyte concentration in the test sample.

Block [19] provides non-invasive methods and apparatus for measurement of the concentration of a selected constituent of a subject's blood. The invention cools a segment of the subject's tympanic membrane and employs the thermal radiation that the subject's **inner ear emits and is transmitted (absorbed) through this cold segment** to directly obtain absorption information related to the concentration of various constituents of blood flowing through the membrane.

Makarewicz [20] shows a method and apparatus for minimizing variations in spectral measurement caused by fluctuations in tissue state by monitoring a selected tissue state parameter spectroscopically and maintaining the selected parameter within a target range. The invention provides a method and apparatus for minimizing the effects in near IR spectral measurements attributable to shifts in skin temperature at a tissue measurement site. Spectroscopic monitoring of skin temperature at the measurement site provides near-instantaneous temperature readings by eliminating thermal time constants. A thermistor positioned at the measurement site provides active control. The spectrometer and the temperature control device are incorporated into a single instrument for noninvasive measurement of blood glucose concentration.

In article [21] the seminal Diabetes Control & Complications Trial Research Group concluded that frequent glucose monitoring is necessary to reduce the

complications of diabetes. However, all glucose monitors available require invasive techniques with the most widely used method of self-monitoring, obtaining blood from a finger prick, causing pain and discomfort which results in poor compliance.

Lawson [22] discovered that skin temperature over a cancer in the breast was higher than that of normal tissue. Thermal imaging (thermography) is a noninvasive diagnostic technique that allows the examiner to visualize and quantify changes in skin surface temperature.

GlucoWatch [23] by Cygnus, Inc. is the only minimally invasive instrument approved by FDA as an adjunctive device to supplement blood glucose testing. The device transdermally extracts interstitial fluid from the skin using iontophoresis. An extremely low electric current pulls interstitial fluid glucose through the skin. However, the GlucoWatch still requires daily calibration of the instrument using the invasive finger-stick method.

CGMS [24] by MiniMed Inc. is a subcutaneous, continuous blood glucose monitoring system that directly records and stores concentration values in memory. This invasive device does not provide measurements directly to the patient and is available for professional use only.

Klonoff [25] and **Koshinsky** [26] provide reviews on approaches for non-invasive blood glucose measurements. In recent years, infrared (IR) spectroscopy has emerged as the analytical method of choice founded on the spectrum of IR frequencies characteristic of the analyte itself instead of relying on reagents and color reactions.

Kajiwara [27] reported using Fourier Transformed Infrared Spectroscopy (FTIR) methods for quantitative measurements of glucose concentration in blood and serum samples at characteristic absorbance peaks.

Different approaches in infrared absorption are described in following references: **Bauer** [28], **Bhandare** [29], **Heise** [30], **Cadet** [31], **Budinova** [32], **Vonach** [33]. None of these devices are commercially available. These devices utilize absorption, transmission, and reflection methods for spectroscopically analyzing blood glucose concentration.

The analytical methods based on Thermal Emission Spectroscopy (TES) are described in book by **Willis** [34] as well as in the following references: **Chase** [35], **DeBlase** [36], **Sullivan** [37], **Keresztury** [38], **Friedrich** [39].

Jensen [40] shows the effects of temperature variation in near infrared (NIR) spectral measurements.

Malchoff [41] shows that if spectral thermal emission measurements are performed in well controlled ambient conditions as described for in vitro experiment, it is not necessary to include additional parameters in calculation of glucose concentration from intensity of glucose thermal emission spectral lines. It shows also clinical results of blood glucose measurements by measuring the infrared radiation from the subject tympanic membrane naturally emitted as heat in a manner similar to a non-contact ear tympanic thermometer. For the measurements in real life conditions, especially for in vivo and non-invasive, one must incorporate necessary environmental and physiological subject's parameters to compensate their influence on spectral measurements.

Planck [42] shows in his fundamental monography the correspondence between the emission and absorption spectra as he theoretically predicted. Planck describes the

difference between absorption spectroscopy and thermal emission phenomena where the entire volume of the emitting body is a source of radiation, which can be measured.

Griffiths in his book [43] shows one of the first thermal emission spectra of chemical interest that of aniline at 30 deg C was shown experimentally in 1965 with its transmittance spectrum for comparison.

REMARKS:

None of the references shows an apparatus for an infrared spectral measurements integrated with temperature and humidity sensors. The invented device integrates ambient temperature sensor, subject body temperature sensor, subject tympanic membrane temperature sensor and ambient humidity sensor. It has the objective to provide the infrared spectral monitor, which is not influenced by environmental conditions such as ambient temperature and humidity as well as by subject physiological condition such as body temperature and size and physiological state of an ear canal.

None of the references provide the spectral analyte specific infrared measurements from this same spot of tissue as non-contact temperature measurements by infrared radiation sensor.

None of the references provide the spectral analyte specific infrared measurements in continuous manner that is integrated with ambient temperature sensor, subject body temperature sensor, subject tympanic membrane temperature sensor and ambient humidity sensor.

None of the references provide the spectral analyte specific infrared measurements in continuous manner that is not influenced by environmental conditions such as ambient temperature and humidity as well as by subject physiological condition such as body temperature and size and physiological state of an ear canal.

To the contrary all the referenced and known as a prior art methods and devices are not integrated with all sensors as in invented improvements of the method and apparatus as described in specification and attached claims.

Very respectfully,

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Sheet 1 of 5

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U. S. PATENT DOCUMENTS					
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	1	US- 5,666,956	09-16-1997	Buchert	all
	2	US- 5,823,966	10-20-1998	Buchert	all
	3	US- 4,797,840	01-10-1989	Fraden	all
	4	US- 4,169,676	10-02-1979	Kaiser	all
	5	US- 5,115,133	05-19-1992	Knudson	all
	6	US- 5,146,091	09-08-1992	Knudson	all
	7	US- 5,179,951	01-19-1993	Knudson	all
	8	US- 5,515,847	05-14-1996	Braig et al	all
	9	US- 5,615,672	04-01-1997	Braig et al	all
	10	US- 5,900,632	05-04-1999	Sterling et al	all
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	20	US- 2002/0038080 A1	03-28-2002	Makarewicz et al	all
		US-			
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	23	"GlucoWatch Automatic Glucose Biographer and Autosensor", Cygnus Inc., prescribing information, available from http://www.glucowatch.com	
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	31	CADET F., "Method for Clasification of Biological FTIR Spectra Prior to Quantitative Analysis", Applied Spectroscopy 50: 1590-1596, 1996	
	32	BUDINOVA ET AL., "Application of Molecular Spectroscopy in the Mid-Infrared Region to the Determination of Glucose and Cholesterol in Whole Blood" Appl. Spect. 51:631-635,1997	
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	41	MALCHOFF et al., "A Novel Noninvasive Blood Glucose Monitor", Diabetes Care 25(12):2268-2275, 2002	
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